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P.O. Box 1420  
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Germany



CUSTOMER

Sample Street

Sample location

### Urgent Field Safety Notice

31<sup>th</sup> July 2023

### Protect Plus Patient Drapes included in CombiSet® and Foliodrape®

Dear Ladies and Gentlemen,

PAUL HARTMANN AG, the legal manufacturer of the Protect Plus surgical drapes included into **CombiSet®**, **Foliodrape®** medical device, is proactively informing you of a field safety corrective action driven by a lower performance of the absorbing pad (produced by the Spunbond Meltblown Spunbond technology) applied on multiple products (**see Annex 1**) by comparison with HARTMANN specifications. However, products are still compliant with the standard EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns.

#### Reason of the FSCA:

Lately, HARTMANN received customer complaints mentioning loose fibers release (see explanatory photo below, right hand side). This situation may happen in rare cases during the surgery via frequent and strong friction over the drapes pad and cannot be noticed prior to the procedure.

In case you observe situations comparable with the situation picture B (below right-hand side), please follow the usual clinical practice to thoroughly irrigate with saline solution and subsequent aspiration of the liquids possibly present in the wound with a cleansing intent of the surgical field.

#### **A. Conform material after rubbing wet    B. Non-conform material after rubbing wet.**



We have investigated and determined that products with article numbers and LOTs according to Annex 1 are currently concerned.

ILN 040 9500 00000 0

Board of Directors/Management Board: Britta Fünfstück  
(Chairwoman of the Executive Board/CEO), François  
Georgelin,  
Stefan Grote, Stefan Müller  
Chairman of the Supervisory Board:  
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As there is a random non-conformity that may generate loose fibers, we kindly ask you to support us by following the below list of actions for the stock in your warehouse.

**Necessary activities:**

- 1. Pass on the safety information to all affected persons and areas in your organization.**  
Please ensure that this urgent safety information is passed on to all people in your organization who need to know about it and to all organizations that have received the affected products.
- 2. Verify if you have products with the article numbers and LOTs according to Annex 1.** Sets can only be used according to instructions in **Annex 3** (ATTENTION LABEL + Patch product on top). Single packed drapes shall be scrapped or returned to HARTMANN using the enclosed reply form **Annex 2** (Customer / Distributor / Wholesaler Response Form).
- 3. Label the concerned Sets from your stock** with the label provided to ensure the users are aware of the additional tasks to do. In case you do not have replacement drapes/patch-over drapes, contact a HARTMANN representative and we will provide additional products.
- 4. Please acknowledge and confirm receipt of this urgent safety information** using the enclosed reply form, **Annex 2** (Customer / Distributor / Wholesaler Response Form) by 15.08.2023.

Please consider that for the short term, future Set deliveries from HARTMANN warehouses will be shipped already labeled with the additional label, together with the required supplementary product. Please use these products according to the instructions in Annex 3.

If you have any further questions, please do not hesitate to contact your HARTMANN office or field staff.

PAUL HARTMANN AG apologizes for any inconvenience this may cause.

Regulatory Affairs / PRRC

Attachments:

**Annex 1 - Potentially affected product list and LOT numbers**

**Annex 2 - Customer / Distributor / Wholesaler Response Form**

**Annex 3 - Label and Patch application instruction for selected products**

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Helps. Cares. Protects.

**Annex 1: Potentially affected products:**

**Single packed products: TO BE SCRAPPED or returned to HARTMANN**

- 9365251 - Foliodrape Protect Plus Surgical drape (175cmx170cm, Foot), adhesive, P16
- 9388023 - Foliodrape Protect Plus Surgical drape, adhesive, crepe (200cmx200cm, Foot), P12

**SETS to apply Annex 3 process (ATTENTION LABEL + Patch product)**

[Enter list of products]

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**Annex 2 – Customer Response Form:**

[Enter Customer address]

**Urgent Field Safety Notice – HARTMANN Foliodrape® Protect Plus Patient Drapes**

We hereby confirm receipt of the Field Safety Notice and the forwarding to all those who need to be aware within our organization or to any organization where the potentially affected products have been transferred.

The result of an examination of our stocks is as follows:

**Please indicate:**

- after thorough examination there is **no stock** of the affected products
- existing Sets on stock have been labeled** as per HARTMANN instructions (fill table below in case additional products/ labels needed)
- existing stock will be returned** to HARTMANN (e.g. Single packed products – fill table below)

| REF (article number) | trade name                              | LOTS      | stock quantity             | Desired Action for product            |
|----------------------|---|-----------|----------------------------|---------------------------------------|
| „number“             | „product name“<br>(customer individual) | „number “ | „Number of primary packs “ | “Return / Label / Replacement needed” |
|                      |   |           |                            |                                       |
|                      |   |           |                            |                                       |

Date: \_\_\_\_\_ Signature: \_\_\_\_\_

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### **Annex 3: Solutions and application instruction for affected sets (e.g. Foliodrape Universal set):**

#### **At your stock location:**

Please place the received ATTENTION LABEL on top of potentially affected sets from customer stock to identify the products that require additional steps before use. Do not cover any relevant information (e.g. Expire Date).



#### **During use of the Set:**

Please cover the affected area (absorption pad marked in yellow in photo below) with an additional product (patch). This additional patch drape will be placed over the current absorption pad, starting from surgical field towards Feet (1) respectively Head / Anaesthesia (2).

- Alternative patch products with other LOT numbers / materials vs. affected ones that can be used when high absorption required:
  - Protect Plus single small drapes: REF 9388003, 9388033, 9388552, 9388562, 9388572, 9365270.
  - Absorption pad: REF 9363261, 9363271, 9363251
- Alternative patch products when low absorption needed: Tape – REF 9363560, or any Protect material drape that fits your needs.



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